K123416

510(k) Summary

SYBRON DENTAL SPECIALTIES

MAR 13 2013

Submitter:

Sybron Dental Specialties, Inc.
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Date Summary Prepared: March 2013

Device Name:

- Trade Name - *Insignia with iTero*
- Common Name - Accessory to Orthodontic Brackets
- Classification Name - Orthodontic Plastic Bracket, per 21 CFR § 872.5470
- Product Codes - Orthodontic Plastic Bracket (DYW), Orthodontic Ceramic Bracket (NJM) and Orthodontic Metal Bracket (EJF)

Devices for Which Substantial Equivalence is Claimed:

- *Insignia*, Ormco Corporation, K121524
- *Biomet 3i Patient Specific Dental Abutments (Encode) Designed Using Cadent iTero Scanner and inLab Software Version v.3.5*, K102209

Device Description:

The *Insignia* software creates a computer model of the patient's dentition based on a stone model, iTero scan file or impression of the patient's dentition. The iTero scanner produces a digital scan of a patient's tooth data as an alternative to the physical dental impressions. *Insignia* operators and the orthodontist use this computer model to determine the placement and/or modification of dental brackets to achieve the intended repositioning of the teeth. Ormco then manufactures foam bracket placement jigs to position the brackets on the patient's

teeth in specific positions prescribed by the orthodontist. The orthodontist uses the foam jigs to place and secure the brackets with a commercially-available dental adhesive.

Insignia with iTero consists of the following components and accessories:
1) Proprietary software that calculates the position of dental brackets based on the dental impressions and treatment plan supplied by the patient's orthodontist.
2) Commercially-available metal, plastic, or ceramic brackets and/or individually modified metal brackets.
3) Patient-specific foam bracket placement jigs to affix the brackets in position.
4) Either commercially-available or patient-specific shaped traditional archwires.
The device does not include the adhesive that affixes the brackets to the teeth.

Indications for Use:

Insignia with iTero is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.

The Insignia Orthodontic System is compatible with the iTero scanner.

Summary of Technological Characteristics:

Insignia with iTero is substantially equivalent to two other legally marketed devices in the United States. *Insignia with iTero* functions in a manner similar to and is intended for the same use as *Insignia* that is currently marketed by Ormco. Additionally, the iTero scanner used with Insignia is the same device that is used by Biomet 3i to manufacture the patient-specific dental abutments as described in below.

Features	***Insignia With iTero***	***Insignia (K121524)***	***Biomet 3i Using Cadent iTero Scanner(K102209)***
Indications for Use	*Insignia with iTero* is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.	The *Insignia* Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.	*Biomet 3i Using Cadent iTero Scanner* is intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to

Features	*Insignia With iTero*	*Insignia (K121524)*	*Biomet 3i Using Cadent iTero Scanner(K102209)*
	The Insignia Orthodontic System is compatible with the iTero scanner.		support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.
Sequence of Treatment Plan	• A 3D digital model is created based on a stone model or a patient's dental impression or an alternate digital impression file generated from the iTero scanner is created and forwarded to Ormco. • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review • Foam bracket placement jigs are manufactured to position the brackets on the patient's teeth as prescribed by the orthodontist • Brackets are adhered to the patient's teeth	• A 3D digital model is created based on a stone model or a patient's dental impression • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review • Foam bracket placement jigs are manufactured to position the brackets on the patient's teeth as prescribed by the orthodontist • Brackets are adhered to the patient's teeth	• A digital impression file generated from the iTero scanner is created. • The digital file is electronically sent to Biomet 3i to design and mill the final abutment.

Features	*Insignia With iTero*	*Insignia (K121524)*	*Biomet 3i Using Cadent iTero Scanner(K102209)*
Manufacturing Method	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of computer software using 3-dimensional models of the patient. In-office software allows the clinician to review, alter and approve desired result and appliances. Software generates code that drives machinery to manufacture the appliances.	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of computer software using 3-dimensional models of the patient. In-office software allows the clinician to review, alter and approve desired result and appliances. Software generates code that drives machinery to manufacture the appliances.	Not applicable.

Non-Clinical Test Data:

Accuracy testing of the digital impression file generated from the *iTero* scanner has been successfully verified to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the accuracy testing to the predicate device, Insignia, the performance of *Insignia with iTero* is deemed to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Ormco Corporation
C/O Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties
1717 West Collins Avenue
ORANGE CA 92867

Re: K123416
Trade/Device Name: Insignia with iTero
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, NJM, EJF
Dated: January 28, 2013
Received: January 31, 2013

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123416

Indications for Use

510(k) Number (if known): K123416

Device Name: *Insignia with iTero*

Indications For Use:

Insignia with iTero is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients, using appliances individualized for the orthodontic patient.

The Insignia Orthodontic System is compatible with the iTero scanner.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MPA Mary S. Runner -S
2013.03.12
13:41:47 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123416